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AND AFFILIATED PARTNERSHIPS

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July 22, 2019

Via ECF

Hon. Judge Claire C. Cecchi
U.S. District Court for the District of New Jersey
Martin Luther King Building & U.S. Courthouse
50 Walnut Street
Newark, NJ 07101

Re: *Microspherix LLC v. Merck & Co., Inc., et al.*, C.A. No. 2:17-cv-03984 (CCC)(JBC)

Dear Judge Cecchi:

We represent Plaintiff Microspherix in the above-referenced case, and pursuant to the Court's August 6, 2018 Order, D.I. 68, submit this joint status letter on behalf of Microspherix and Defendants Merck Sharp & Dohme Corp., Merck Sharp & Dohme B.V., and Organon USA, Inc. (collectively, "Defendants" or "Merck").

Case Background and Current Status

This is an action for patent infringement filed on June 5, 2017, D.I. 1, as subsequently amended October 18, 2017, D.I. 27. Microspherix alleges that Merck infringes U.S. Patent Nos. 6,514,193; 8,821,835; 9,636,401; and 9,636,402, through its manufacture, use, sale, and/or offer to sell an implantable contraceptive known as Nexplanon, as well as by providing accompanying prescriber and patient information instructing use of this implant. On October 25, 2017, Merck filed a partial Motion to Dismiss Count II of the Amended Complaint, directed to the allegations regarding the '193 patent. D.I. 28. Merck's motion is fully briefed, D.I. 33, 35–36, and the Court held oral argument on June 19, 2018. *See* D.I. 56. A decision on Merck's motion has not yet issued, and Merck has not yet answered the Amended Complaint.

Between December 2017 and June 2018, Merck filed four *Inter Partes* Review ("IPR") petitions alleging that the asserted claims of the patents-in-suit are invalid as obvious over certain printed prior art publications; IPR proceedings were instituted in response to each of those petitions:

- IPR 2018-00393 regarding U.S. Patent No. 9,636,402 (claims 1–19);
- IPR 2018-00402 regarding U.S. Patent No. 9,636,401 (claims 1–5 and 9–25);
- IPR 2018-00602 regarding U.S. Patent No. 8,821,835 (claims 1–4, 9–12, and 14–20); and

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- IPR 2018-01288 regarding U.S. Patent No. 6,514,193 (claims 1–2).

On stipulation by the parties, the Court entered an Order on August 6, 2018, staying this action pending the conclusion of the IPR proceedings. D.I. 68. At that time, the parties had complied with Local Patent Rules 4.1 and 4.2, but had not prepared or submitted to the Court a joint claim construction statement.

On April 15, 2019 the PTAB cancelled, upon Microspherix's request, the challenged claims of the '193 Patent. On July 8, 2019, the PTAB issued final written decisions in the remaining three IPR proceedings. The PTAB held that the challenged claims of the '835 and '401 Patents, and two of the challenged claims of the '402 patent, had not been proven unpatentable. The PTAB held that the remaining challenged claims of the '402 patent were unpatentable.

The parties met and conferred on July 18, 2019 but were unable to reach agreement regarding how to proceed with the present action. The parties present their respective positions below.

The Parties' Positions Regarding How to Proceed with the Action

Microspherix's Position

The Original Basis for the Stay No Longer Exists So the Case Should Proceed. In light of the overwhelming affirmance of the validity of the asserted claims—39 claims across three patents—the original basis for the Court's stay is now gone. The stay should be lifted and the prior schedule resumed with appropriate adjustment of the deadlines to account for the stay. There is no good reason for the entire case to be halted, with literally no progress occurring for at least the next year, simply based on Merck's remote hope that it will be 100% successful on appeal.

This lawsuit has been pending over two years. D.I. 1 (June 5, 2017). Defendants filed several IPRs arguing all 56 asserted claims of the '401, '835, and '402 Patents should be cancelled. Subsequent to institution of those IPRs, Defendants told the Court that "if any of Plaintiff's claims emerge from IPR, the stay will streamline future proceedings before the Court as the parties' positions will be crystalized and the scope of their contentions likely narrowed by trial in the IPR proceedings." D.I. 58. The PTAB has now fully evaluated Defendants' arguments and rejected them for 39 of those claims (67%), including all challenged claims of the '401 and '835 Patents. For purposes of moving forward, Microspherix will streamline its case by asserting only the 39 upheld claims.

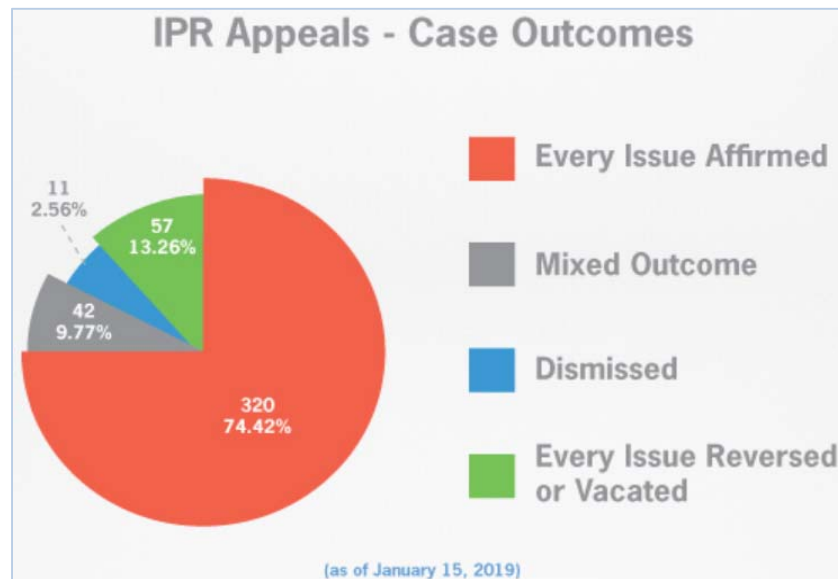
Once IPR is instituted, it is fair to say that the challenged patent claims are in peril: all claims are cancelled by the PTAB in almost two-thirds of IPR proceedings. *See* PTAB Trial Statistics (2/2019), at 10, *available at* <https://tinyurl.com/y26va3en>. But after Microspherix's resounding success before the PTAB, the statistics no longer favor either Merck or a stay. Merck's

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chances for invalidation of the 39 affirmed claims has gone from a theoretical probability (before the PTAB decision) to a remote possibility (now on appeal). *See Network-I Sec. Sols., Inc. v. Alcatel-Lucent USA Inc.*, 2015 WL 11439060, at *3 (E.D. Tex. Jan. 5, 2015) (“[I]f any presumption is now applicable to the asserted claims that survived the IPR proceedings, is that they are valid and enforceable.”) (citing 35 U.S.C. § 282 and cases). The rationale for the Court’s original stay decision—evaluating what the outcome is likely to be—now demands that the stay be lifted and the case schedule resumed.

Merck’s Chances on Appeal Are Remote and Thus Do Not Justify Further Delay. Despite this action now being stayed for a year, Defendants argue this case should remain stayed pending appeals of unidentified “legal and factual errors.” But continuing the stay will result in substantial prejudice to Microspherix (*see below*) and only delay the inevitable resumption of the case. Recent statistics show that the PTAB’s decisions are **completely affirmed** in 75% of IPR appeals, at least some claims are affirmed in over 85% of appeals, and outright reversal occurs in a mere 5% of appeals:¹



See Federal Circuit PTAB Appeal Statistics (1/15/2019), FINNEGAN, *available at* <https://tinyurl.com/y4tshfqj>; *see also* Federal Circuit Appeals from the PTAB (2018), STERNE KESSLER, at 1, 13, *available at* <https://tinyurl.com/yyz8b2ju> (“[T]he Court affirmed about 75% of all decisions, remanded about 20%, and **reversed only 5%**”); *see also Personal Audio LLC v. Google, Inc.*, 230 F. Supp.3d 623, 627, 629 (E.D. Tex. 2017) (lifting stay, noting 7% reversal rate

¹ Merck relies on its counsels’ own statistics for just **one year** (2017–2018), and these statistics do not appear limited to just IPR agency decisions unlike those provided by Microspherix.

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and that “courts routinely review statistical research from the Federal Circuit to determine how a case may be delayed by staying a case through appeals of PTO or PTAB decisions.”) (citing cases).

Merck’s chances of success are even worse than these dire statistics. When the Federal Circuit reverses the PTAB it typically does so when the PTAB has found claims unpatentable—not when the PTAB has confirmed them. *See, e.g.,* MCDERMOTT WILL & EMERY, “Federal Circuit Issues **Rare Reversal** of PTAB IPR Decision Confirming Patent Claims,” October 2, 2017, *available at* <https://tinyurl.com/y267tzn4>. Merck’s recalcitrance in even identifying any actual factual or legal error is further telling, suggesting Merck merely disagrees with the PTAB’s decision, rather than having any meritorious appellate issues (let alone one that cuts across all 39 affirmed claims). Indeed, in the Notices of Appeal filed today by Merck, it merely states that the issue on appeal is “[w]hether the Board erred in determining that the challenged claims ... have not been shown to be unpatentable.” Notices of Appeal, IPR 2018-00393 (Paper 44), 2018-00402 (Paper 45), 2018-00602 (Paper 44), at 2.

Microspherix Will Be Prejudiced by a Continued Stay. Continuing to stay this case severely prejudices Microspherix. A stay will create incalculable evidentiary hurdles as witnesses’ memories fade or even disappear altogether. For instance, Merck alleges a prior invention defense based on events occurring over 20 years ago, raising the distinct possibility of disappearing evidence and fading memories. Microspherix should be allowed to depose these individuals before more time passes or they become unavailable. *Elm 3DS Innovations, LLC v. Samsung Elecs. Co.*, 2018 WL 1061370, at *2 (D. Del. Feb. 26, 2018) (lifting stay and noting the prejudice to Plaintiff to present evidence at trial and risk of additional evidentiary harm); *Personal Audio LLC*, 230 F. Supp.3d at 627 (“Life is uncertain; experts [, witnesses] and lawyers change professions, retire, and die. [Merck]’s arguments certainly do not outweigh the risk of prejudice that would result from indefinitely staying the case past the thirteen months that have already passed”).

In addition, Merck’s allegations of invalidity continue to create a cloud over Microspherix’s ability to license its intellectual property—a prejudice that is compounded by the fact that Microspherix’s patents will start expiring in the first half of 2021 and thus are likely to expire prior to reaching trial should the stay continue. 230 F. Supp.3d at 627 (“[T]he fact that a major corporation like [Merck] evidently believes the patent is not enforceable creates a cloud over Plaintiff’s ability to license its intellectual property.”). As courts have recognized, this prejudices patent owners in litigation as well as in their business generally. *See, e.g., ACQIS, LLC v. EMC Corp.*, 109 F. Supp. 3d 352, 359 (D. Mass. 2015) (lifting stay pending IPR appeal and noting that although patent owner was a “non-practicing entity that does not compete directly with [Merck]” a stay “would prejudice [Microspherix] in this litigation as well as its business generally, especially given that [its] asserted patents will begin expiring...” and, as here, Merck “never mentioned the possibility of ... extending the stay pending such an appeal” beyond the parties reporting their intent to file appeals); D.I. 68; *DataTreasure Corp. v. Fiswerv, Inc. et al.*, C.A. 2:13-CV-431-JRG-RSP, D.I. 616, at 12 (E.D. Tex. August 14, 2014) (noting continued “extension of the suit may

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consume [Microspherix's] resources, denying it the opportunity it otherwise might have had to enforce its patents."); *Network-I Sec. Sols., Inc.* 2015 WL 11439060, n. 9 ("[R]equiring such delay through exhaustion of appeals could encourage 'abuse of *inter partes* review [and appeals thereof] as a tool for tactical delay.'") (quoting *Universal Electronics, Inc. v. Universal Remote Control, Inc.*, 943 F. Supp. 2d 1028, 1030 (C.D. Cal 2013)).

In response, Merck claims there is "no urgency" because this lawsuit was filed in 2017 after the accused product entered market. But this ignores that Microspherix filed the lawsuit within two months of the asserted '401 and '402 patents issuing. Moreover, the absence of direct competition does not negate the actual prejudice to Microspherix in "delay[ing]...its ability to have [Microspherix's] allegation of patent infringement adjudicated in this court...especially where the decisions being appealed favor Plaintiff [as here]..." *Elm 3DS Innovations, LLC*, 2018 WL 1061370, at *2 (noting the "real prejudice" such continued delay imposes on a Plaintiff).

If the stay continues, a trial on the merits may not occur until *six years* after this case was filed, rendering it one of the longest running patent cases in this district, and far above Your Honor's ~2 year average time to termination in patent cases over the past five years, as well as the ~3 year time to termination by trial in this district.² Indeed, Merck's own statistics suggest the average time to decision for the appeal may be approximately *19 months*. See *infra*, GIBSON DUNN Statistics, at 3 (average time for lower tribunal decision to federal circuit decision of *572 days*). If this case remains stayed, the prejudicial effect on Microspherix will be substantial, as it will have waited nearly six years, if not more, after it filed its Complaint for this case to resume. "Such a pace [is] inappropriate for the prompt dispatch of judicial business." *Signal IP, Inc. v. Ford Motor Co.*, 2015 WL 5719671, at *6 (E.D. Mich. Sept. 30, 2015) (denying motion to stay case when unduly prejudicial to plaintiff to wait two-and-a-half years after the filing of the complaint for the case to get started). Given how unlikely it is that Merck will be able to accomplish on appeal what it was unable to accomplish before the PTAB, the case schedule should be resumed.

The Mere Possibility of Simplification Does Not Warrant a Continued Stay. Courts have recognized that the pendency of an appeal may "complicate matters" if a PTAB decision is vacated or reversed, but that these "complications [] (if they come to pass)" are ones Merck "will have to live with, having taken their best shot at the PTAB and lost." *Elm 3DS Innovations, LLC*, 2018 WL 1061370, at *2; *id.* at 5 ("And while it is of course possible that the Federal Circuit will come to a different conclusion than did the PTAB, the "mere possibility (as opposed to 'reasonable likelihood') that the asserted claims could be invalidated [after an] appeal and [that this would]

² Information based on official docket records of the Federal Circuit (New Jersey District Court in Patent Cases), January 2014–March 2019, as reported by *LegalMetric* relying on "Average Time to Termination by Judgment" chart and average "Time to Termination" chart. *LegalMetric* has provided permission to rely on reported data provided appropriate citation be given. Microspherix has provided counsel for Merck with the reported data.

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result in simplification is too speculative to be given much weight.”) (quoting *Network-I Sec. Sols.*, 2015 WL 11439060, at *3); *see also, e.g., Zoll Med. Corp. v. Respironics, Inc.*, 2015 WL 4126741, at *1 (D. Del. July 8, 2015) (stating that “pendency of an appeal from the IPR, and the possibility that the Federal Circuit may reverse the PTO (and thereby simplify this litigation by, presumably, making it disappear), is not, in and of itself, a sufficient basis to make [Microspherix]... continue to wait to enforce patent rights that it currently holds.”); *Juno Therapeutics, Inc. v. Kite Pharma*, 2018 WL 1470594, at *7 (C.D. Cal. Mar. 8, 2018) (C.D. Cal. Mar. 8, 2018) (denying stay pending appeal when claims were confirmed because “the Federal Circuit’s determination would not be immediately dispositive unless it chose to reverse the Board’s determination—an improbable result”).

In this case, “[i]n light of the Final Written Decisions, where the PTAB has already analyzed the evidence and articulated its decision after painstaking review, the purpose of the stay has already been fulfilled. In this situation the mere possibility (as opposed to ‘reasonable likelihood’) that the asserted claims could be invalidated or amended on appeal and then result in simplification is too speculative to be given much weight,” *Personal Audio LLC*, 230 F. Supp.3d at 628 (E.D. Tex. 2017); *see also One No. Corp. v. Google Inc.*, 2012 WL 1493843, at *1 (S.D. Ind. Apr. 26, 2012) (denying stay pending appeal of reexamination to BPAI or Federal Circuit stating “maintaining the stay to await the remote chance that the issues would be further simplified on appeal is insufficient to keep the stay in place, especially since [Merck] has not proffered any new evidence that is likely to produce a different result.”).

The Stage of the Proceedings Warrants Lifting of the Stay. Contrary to Merck’s assertion, the current stage of these proceedings warrants lifting the stay. The parties have crystallized the legal theories of the case—indeed, Merck’s best shot at invalidity has been rendered a nullity—conducted significant document discovery, and are primed to begin the *Markman* claim construction process. *See, e.g., Milwaukee Electric Tool Corporation v. Hilti, Inc.*, 2016 WL 7495808 (E.D. Wis. 2016) at *2 (lifting stay despite nascency of case, finding that while “substantial discovery remains to be done in this case” that “until the stay in this case is lifted, there will always be a great deal of discovery remaining”); *see also Virginia Innovation Sciences, Inc. v. Samsung Electronics Co.*, 983 F. Supp. 2d 713, 753 (E.D. Ca. 2014), reconsid. denied (May 2, 2014) (“[T]he preclusive effect of a PTAB final determination is triggered when the PTAB issues its final written decision—regardless of whether an appeal is taken to the Federal Circuit.”); *Network-I Sec. Sols.*, 2015 WL 11439060, at *4 (same). In view of the substantial prejudice to Microspherix that further delay would create, the parties should proceed quickly to resolve the merits of this case.

Merck’s Offer to Expedite is Illusory. Merck claims it intends to expedite its appeal, but this does not change the analysis, and its offer is hollow in any event. First, despite purporting to have identified “legal and factual errors,” it only filed its Notice of Appeal—which identifies no specific errors—today, soon after Microspherix sent a draft to Merck of this letter in which it noted

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Merck had not yet taken any action. While Merck has now been spurred to action, its early filing of a Notice of Appeal at best may reduce the 19-month average time to decision by about a month. *See infra*, GIBSON DUNN Statistics, at 3 (average time for lower tribunal decision to federal circuit decision of 572 days).

Further, Merck's stated intent to request the Federal Circuit condense the briefing schedule and hear oral argument *immediately* is unrealistic and prejudicial. Merck will have five months to file its initial brief, and then seeks to cut Microspherix's responsive briefing time by 25%—while not reducing its time for a reply brief at all. *See* Ex. A (email correspondences regarding Merck's proposal). It then further asks that oral argument be held in as little as three days after Merck submits its final brief (giving Microspherix no time to prepare for oral argument). In any event, the Federal Circuit is unlikely to agree to expedite oral argument, let alone hear oral argument the first calendar week after briefing is complete. *See* Practice Notes (“[M]otions to expedite proceedings are *not routinely granted*,” are appropriate in appeals involving injunctions (unlike here), and are styled “Emergency Motion[s]”).

Finally, Merck also waited approximately six months (for its first IPR petition) and almost a year (for its final IPR petition) after the complaint in this case was filed—nothing suggests that Merck will now act any quicker than it has in the past. *See Signal IP, Inc.*, 2015 WL 5719671, at *6 (noting prejudice to Plaintiff in delaying “having its case timely resolved” and that such delay is “a consideration here, because many of the *inter partes* review proceedings were not filed until almost a full year after [Microspherix] filed its complaint in this case.”).

Microspherix's Pending Patent Application Does Not Warrant a Continued Stay. As Merck acknowledges, the USPTO has confirmed the patentability of Microspherix's pending '293 application (*see infra*) and that this application “has the same specification and includes largely overlapping claim limitations as the patents-in-suit.” Because of this, there is little concern that the parties would have to expend significant resources or time in preparing any necessary supplemental filings, or that new claim construction issues would arise. In any event, Microspherix has not reached a decision on whether to assert this additional patent should it issue. Merck has been aware of, and clearly tracked the progress of, the '293 application, and therefore should be prepared to address the merits of this patent (should Microspherix assert it) that is largely identical to the already asserted patents-in-suit.

Merck's Case Law is Distinguishable. Merck's case law is inapposite. *Depomed* is both distinguishable and an exception to the weight of the case law. “Other courts have noted the exceptional nature of *Depomed*, insofar as it “took only 191 days, the third-shortest amount of time of the over 80 cases included in the analysis” of the normal predicted course of an appeal. *ACQUIS, LLC v. EMC Corp.*, No. 14-CV-13560, 2016 WL 4250245, at *2 (D. Mass. Aug. 10, 2016) (lifting stay pending IPR appeal). Moreover, the court in *Depomed* only extended the stay *after* the emergency schedule had been set by the Federal Circuit. Even if Merck requests a similar schedule

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(it has not yet), the chances of a similarly expedited appeal are slim given the explosion of appeals seen at the Federal Circuit since *Depomed* was decided. Notwithstanding Merck's attempt to change the optics of the present stay, the reality is that any appeal will still be a lengthy process that will exacerbate the irreparable harm to Microspherix. With respect to Merck's remaining cases, they do not address the merits of lifting a stay pending the outcome of an appeal to the Federal Circuit, but instead relate to the *institution of a stay*. Merck's additional authority provides no guidance as to whether, *in this case*, it is appropriate to continue to stay the action after the PTAB has rejected Merck's arguments and upheld the validity of 39 claims. As explained herein, it clearly is not.

The Parties Can Account for Any Determination by the Federal Circuit. Even if Merck were able to overcome its dismal odds on appeal and win on some of the 39 claims held valid by the PTAB, this still does not warrant a stay of the proceedings. The parties can account for any appeals to the Federal Circuit in structuring the case schedule and are well aware of the legal and factual issues at stake. *Elm 3DS Innovations, LLC*, 2018 WL 1061370, at *2 ("The parties, in preparing a proposed Scheduling Order, can work to take into account the likely timing of a Federal Circuit appellate decision...").

Moreover, the PTAB's final decisions did not turn on any disputed claim construction, nor has Merck identified any claim construction issue that would be dealt with by the Federal Circuit. *See Milwaukee Electric Tool Corporation*, 2016 WL 7495808 at *2 ("The Court already has the benefit of the expert guidance of the PTAB, and [Merck] does not explain why the insight of the Federal Circuit would be substantially more helpful beyond the prospect of reversing the PTAB's ruling."). As such, the parties can proceed through *Markman*, and begin conducting depositions and expert discovery. For example, there are numerous issues entirely independent of the IPRs, including Merck's allegations regarding infringement, prior invention, derivation, written description, enablement, and indefiniteness, "making the idea of further simplification illusory." *See* 230 F.Supp.3d at 628–629.

Conclusion. Defendants have identified no colorable error in any of the PTAB's three decisions that merit reversal, and none exist. Instead, Merck "took its best shot at the PTAB and lost," and Microspherix should be given its day in court soon, and not six or more years from when this case was first brought. *See Elm 3DS Innovations, LLC*, 2018 WL 1061370, at *2. This action can continue to stand still for well over a year or more, or it can move forward for a "speedy" determination as the first rule of the Federal Rules of Civil Procedure require. As needed, the parties can readily make any necessary adjustments to the case and schedule in view of appellate proceedings. Merck's continued efforts to delay this case are unwarranted and deprive Microspherix of its ability to enforce its patent rights, which have now been confirmed as valid after careful consideration by the PTAB.

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Accordingly, Microspherix respectfully proposes that the Court lift the present stay and order the parties to meet and confer regarding an appropriate path forward.³

* * *

Merck's Position

Merck proposes that the Court maintain the stay, as contemplated in the Court's Order of August 6, 2018, "through the conclusion of the IPR Proceedings," including through Merck's appeals from the Board's decisions in IPR2018-00393, -00402, and -00602. D.I. 68. While the IPR proceedings have already narrowed the case, the resource-preservation that initially motivated the stay of this nascent case is still present pending Merck's appeal. The hypothetical prejudice Microspherix sets forth is entirely belied by its own delays. The Court should maintain the stay for at least the reasons set forth below.

The appeal of a single issue may entirely dispose of the case. Thus far, the IPR proceedings have resulted in 40% of the asserted claims being cancelled or held unpatentable. The IPRs have not been an "overwhelming affirmance" of the claims in dispute. The Board found that the prior art Merck raised in its grounds for unpatentability indisputably disclosed each and every limitation of Microspherix's claims. *See* Ex. B (IPR2018-00393) (Paper 43). The Board furthermore identified issues with the written description of Microspherix's claims, including some it identified *sua sponte*. *See, e.g., id.* at 52. While the Board rejected certain grounds for invalidity as to the '401 and '835 patents, as well as claims 6 and 9 of the '402 patent, it did so based primarily on a narrow issue regarding the motivation to combine Merck's references—an analysis that Merck intends to appeal as legally erroneous. Merck has filed Notices of Appeal to the Federal Circuit seeking to reverse this legal error, which is dispositive of the Board's decision of every asserted claim that survived the IPR proceedings. Microspherix's citation to *Network-1* is entirely inapposite. There, the Board's decision not only identified a claim limitation as missing from the prior art but also granted the plaintiff 14 *new* claims in an *ex parte* reexamination, which the court explained "were not part of the IPR proceedings and therefore cannot be invalidated by appeal." 2015 WL 11439060 at *2. Here, all of the remaining asserted claims are implicated by this single legal issue, and should Merck prevail, this entire case will therefore likely be resolved.⁴

³ Merck's cries of prejudice regarding the preparation of this letter are unfounded, and if any party has been prejudiced in the process, it is Microspherix. Microspherix received Merck's final insert, which substantially revised its prior positions, at 9:35 PM today, and which included additional arguments respecting the factual record and legal authority that Microspherix disagrees with. In the interest of timely complying with this Court's Order, Microspherix submits its position, above, that was submitted to Merck this morning at 9:01 AM (with a minor revision at 6:18 PM), the first business day after receiving Microspherix's last proposed insert. Microspherix respectfully requests oral argument to address Merck's arguments and characterizations if helpful to the Court.

⁴ Merck reserves its right to appeal all other errors it identifies in the Board's decisions.

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Microspherix also spins the relevant statistics in a way that is not relevant to the facts of this case. In the 2017–2018 term, the Federal Circuit only affirmed in their entirety 59% of the PTAB’s rulings related to obviousness. *See* Federal Circuit Year in Review 2017/2018, GIBSON DUNN, November 26, 2018, <https://tinyurl.com/y4xrouco>, at 13. Microspherix’s statistical assertions are not to the contrary. Microspherix cites statistical summaries of the entire universe of appeals that have been raised since the inception of IPRs in 2012. These summaries fail to take account of any current trends in the reversal rate as patent law is developed at the PTAB and Federal Circuit. Microspherix also fails to account for the specific issue to be raised on appeal. Here, where the potentially case-dispositive issue is the Board’s obviousness analysis (a question of law), the above statistic shows that the Board is far more likely to reverse than Microspherix represents. *Id.* (showing a mere 59% of obviousness determinations fully upheld on appeal). Furthermore, Microspherix’s conjecture that the Federal Circuit “rarely” reverses determinations upholding patent claims is entirely unsupported. The citation Microspherix advances for this proposition merely provides an anecdote of one appeal. *See* MCDERMOTT WILL & EMERY, “Federal Circuit Issues Rare Reversal of PTAB IPR Decision Confirming Patent Claims,” October 2, 2017, available at <https://tinyurl.com/y267tzn4>.

A stay pending appeal will further simplify the case and will promote efficient use and conservation of the Court’s and the parties’ resources. Even in the event the Federal Circuit does not reverse the Board’s decision, the Federal Circuit’s opinion may substantially impact both claim construction and the validity of Microspherix’s patents under 35 U.S.C. § 112. Despite Microspherix’s assertion that the Board’s opinion did not “turn on any disputed claim construction,” the Federal Circuit’s analysis of Merck’s appeals may turn entirely on the scope of Microspherix’s claims.

Based on current averages for the duration of Federal Circuit appeals, the appeals are likely to be decided prior to trial in this case even absent a stay and absent expediting of the appeal, potentially causing the parties to have to re-exchange expert reports or other pre-trial submissions to reflect the Federal Circuit’s decision. Upon docketing of the case at the Court of Appeals for the Federal Circuit (typically within a few days of Filing the Notices of Appeal, which were filed today, July 22, 2019), Merck will file a motion requesting the appeals be expedited.⁵ For this reason, Microspherix’s citation to *Personal Audio*, where the defendant delayed the appellate schedule with a request for a rehearing from the Board, is inapposite.⁶ Specifically, Merck will request that the briefing schedule be compressed and that oral argument be held by the Federal Circuit at the earliest possible date after briefing is completed. Merck has specifically solicited

⁵ Microspherix is well aware that Merck’s Notices of Appeal were in progress before any reference to them by Microspherix was inserted into in this joint submission; any statements implying otherwise are wrong.

⁶ In *Personal Audio*, the appeal also failed to encompass all of the asserted claims and could therefore not resolve the entire case.

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Microspherix to join in expediting the appeal, but Microspherix has declined. Microspherix misrepresents the nature of Merck's proposal by suggesting that Merck would not shorten its own time to reply. Merck actually offered to shorten the periods for filing "each brief," discussing the opening and responsive briefs as a "[f]or instance" example of the timing. *See* Ex. A at 1. Regardless of Microspherix's characterizations or decision not to join Merck on this matter, Merck will self-expedite the appeals by filing its own briefing (both opening and reply) on an accelerated schedule in order to minimize the duration of the stay. As noted, Merck will also request an early oral argument in the case.

Every single claim at issue in the district court proceedings is the subject of the appeal in this matter. Microspherix cites numerous cases where claims were asserted in the district court that were not the subject of the appeal from the IPR decision. *See, e.g., Network-I Sec. Sols., Inc. v. Alcatel-Lucent USA Inc.*, 2015 WL 11439060, *4 (E.D. Tex. Jan. 5, 2015) (finding newly asserted claims brought into the litigation, beyond the claims previously instituted on IPR, "foreclose[d] the possibility" that an appeal from the Board's Final Written Decision could lead to "ultimate simplification" of the issue); *Pers. Audio LLC v. Google, Inc.*, 230 F. Supp. 3d 623, 629 (E.D. Tex. 2017) ("Because the PTAB denied instituting IPR on all of the claims of all of the patents, the ultimate kind of simplification—a complete resolution of the issues—is impossible here."); *Elm 3DS Innovations, LLC v. Samsung Elecs. Co.*, No. CV 14-1430-LPS-CJB, 2018 WL 1061370, at *2 (D. Del. Feb. 26, 2018) ("As Plaintiff notes, no matter what happens with the pending appeal, the case will certainly go forward unaffected as to one of the patents-in-suit: the '581 patent, which is not the subject of appellate review."); *Signal IP, Inc. v. Ford Motor Co.*, No. 14-CV-13729, 2015 WL 5719671, at *4 (E.D. Mich. Sept. 30, 2015) ("[T]he Court notes that the Plaintiff has agreed to dismiss the asserted claims of the '601 and '375 Patents that are at issue in the inter partes review proceedings and will seek to add different claims that are not at issue in the inter partes review proceedings."). These cases are not helpful here, where a narrow issue that is regularly reversed could dispose of the entire case. The Court should conserve its and the parties' resources by maintaining the stay.

Maintaining the status quo by not lifting the stay through the appeal from a PTAB decision "would not be an unusual result," as courts in this district have previously held. *Depomed, Inc. v. Purdue Pharma L.P.*, No. CV 13-571 (MLC), 2016 WL 50505, at *2 (D.N.J. Jan. 4, 2016) (granting stay pending expedited appeal from PTAB decision over objection of opposing party); *Richmond v. Lumisol Electrical Ltd.*, C.A. No. 3-13-cv-01944, D.I. 226 at 6 (D.N.J. Sept. 21, 2015) (granting stay pending IPR and any subsequent appeals); *see also Trs. of Columbia Univ. v. Illumina, Inc.*, 620 Fed. Appx. 916, 917–21 (Fed. Cir. 2015) (determining appeal from IPR decision while district court action below was stayed); *Ultratec, Inc. v. CaptionCall, LLC*, 611 Fed. Appx. 720, 720 (Fed. Cir. 2015) ("[T]he district court granted a stay of the litigation pending a final inter partes decision on the validity of all the claims-in-the-suit, including the exhaustion of any appeals.").

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Microspherix's imminent addition of a patent to this case weighs in favor of a continued stay. An additional and independent reason to maintain the status quo and continue the stay pending appeal is the recent issuance of a Notice of Allowance by the USPTO of another closely-related patent application filed by Microspherix, U.S. Patent Application No. 15/492,293 ("the '293 application"). This application is a continuation of the patents-in-suit; it has the same specification and includes largely overlapping claim limitations as the patents-in-suit. Prior to the current lawsuit, Microspherix identified the '293 application in correspondence to Merck, threatening to wield it against Merck upon issuance. 7/25/17 Letter to Krovatin, Ex. C. In the parties' Proposed Joint Discovery Plan of February 13, 2018 (submitted to the Court prior to the institution of the stay), Microspherix expressly stated that "Plaintiff may seek to amend their complaint to further allege infringement of [the '293 application], should it issue as a U.S. patent prior to the completion of discovery. Consideration of this additional patent would serve the interests of judicial economy because the anticipated claim scope and subject matter would track the pending asserted patents and would not impose undue burden on Defendants."

Given the recent Notice of Allowance on the '293 application, it would appear its issuance may be imminent. It would be wasteful of the parties' and the Court's resources to proceed with claim construction, supplemental infringement and invalidity contentions, and/or fact and expert discovery on the patents-in-suit, only to have to start again with respect to Microspherix's new related patent.

Within three days of the PTAB's issuance of its Final Written Decisions for the patents-in-suit, Microspherix sought to amend the claims in the '293 application injecting into the allowed claims the very same issue that will be a primary subject of Merck's pending appeals of the PTAB decisions. Thus, extending the stay until the conclusion of the appeals will resolve this key issue with respect to Microspherix's new patent just as it will with respect to the current patents-in-suit.

Microspherix will suffer no prejudice if the stay is continued. Microspherix filed this suit in 2017, 14 years after the first asserted patent issued and almost 6 years after the accused Merck product was launched. Microspherix's own delay demonstrates there is no urgency in resolving the issues in this case. Microspherix's counter-argument that the latest members of the asserted patent family ('401 and '402 patents) only recently issued is unavailing—Microspherix alleges that Merck's product infringes the '193 and '835 patents, both of which stem from the same priority document as all of the asserted patents, and both of which issued to Microspherix many years prior to bringing this case.

Microspherix does not make, use, or otherwise exploit any products covered by the remaining asserted claims, and accordingly, Microspherix does not seek any injunctive relief. Microspherix's suggestion that this case is somehow dampening its ability to license the patents-in-suit is without support and contrary to Microspherix's own discovery responses. Merck has several outstanding RFPs to Microspherix related to licensing, including any "offer or attempt to

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license” any of the Microspherix patents. Despite these RFPs and a follow-up letter to Microspherix’s counsel specifically calling for such documents if any exist, Microspherix has not produced a single such document or even identified a potential licensee for its patents. For this reason, Microspherix’s reliance on *ACQIS* and *DataTreasury*, where plaintiffs had already sued numerous other market participants and potential licensees, is entirely misplaced. Furthermore, as Microspherix itself quotes from *ACQIS*, the parties there never contemplated extending the stay through appeal. Here, the stay order itself recognizes that possibility, requiring the parties to request the stay be lifted following the PTAB’s final decisions.

Microspherix also speculates that there is a “possibility of disappearing evidence and fading memories” if the stay is maintained pending appeal, but that kind of sheer speculation does not amount to evidentiary prejudice. *See, e.g., Meyers v. Asics Corp.*, 974 F. 2d 1304, 3018 (Fed. Cir. 1992) (rejecting claim of evidentiary prejudice) (“Conclusory statements that there are missing witnesses, that witnesses’ memories have lessened, and that there is missing documentary evidence, are not sufficient.”).

Microspherix also misrepresents the time-impact of Merck’s appeal, and ignores Merck’s commitment to expedite. Assuming the longest average time for the appeal and accounting for the case schedule as it existed prior to the present stay, the pretrial conference in this case would fall only 4.5 years after the complaint was filed, not 6 years. Microspherix cites statistics regarding average time to “termination,” ignoring that most cases are terminated by judgments other than trial on the merits. The very document Microspherix cites demonstrates that the average time to a claim construction decision alone is more than 3 years. *See LegalMetric* at 69. Any delay caused by the appeal is commensurate with the delay that Microspherix has already made of its own choosing, and is otherwise outweighed by the potential to simplify the case even further than the stay pending IPR proceedings already has.

Furthermore, these proceedings are still in their early stages. No claim construction briefs have been submitted, fact discovery is nascent, the parties have not crystallized a single dispute with respect to the written discovery, not a single deposition has been taken, and no expert discovery has started. For these reasons, the Court should deny Microspherix’s request to lift the current stay.

Merck requests additional briefing on Microspherix’s request to lift the stay. In the Stipulation and Order Staying Case (D.I. 68), the Court contemplated two filings following the PTAB’s written decisions: (1) a filing by either party requesting the Court to lift the stay and setting forth the parties’ positions, and (2) a joint status report. The first filing has no specified deadline, while the second (the current joint filing) is due 10 business days (14 calendar days) after the issuance of the PTAB’s decisions—*i.e.*, today. As demonstrated in the attached email chain (Ex. D), Microspherix waited nine calendar days after the PTAB issued its written decisions to provide Merck for the first time with a draft of today’s joint filing, including a 500-word section

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entitled “Microspherix’s Position.” Then, after Merck provided its section, Microspherix provided to Merck for the first time *this morning* a new version of “Microspherix’s Position” that is over 3,000 words (the equivalent of an 11-page brief), asking Merck to respond to all of Microspherix’s new arguments in less than a day. *Id.* As set forth in the attached correspondence, Merck proposed to Microspherix that, given the volume and last-minute nature of Microspherix’s arguments, the parties simply decouple today’s joint status report from the briefing on whether the Court should lift the stay—as specifically contemplated by the Court’s Order Staying Case—and that the stay issues be briefed on a separate schedule, affording Merck an opportunity to respond in full. *Id.* Microspherix refused, now characterizing its earlier draft of “Microspherix’s Position” as just a “preview of [its] position statement” and insisting, over Merck’s objection, that Microspherix would proceed, as it has, to include the above new briefing on the stay issue in today’s joint status update. *Id.*

Microspherix’s withholding of its actual positions and arguments regarding lifting the stay until the morning of today’s filing obviously prejudices Merck’s ability to reasonably respond in a manner that will aid the Court. While Merck has addressed what it can of Microspherix’s briefing on short notice, Merck requests that it be granted an opportunity to respond fully by filing an Opposition letter by Monday, July 29.⁷

If the Court would benefit from a status conference to discuss any of the foregoing issues, Merck is available at the Court’s convenience.

* * *

The parties thank the Court for its attention to this case and remain available to the Court if Your Honor has any questions.

⁷ After receiving Microspherix’s expanded brief this morning, Merck proposed to Microspherix that, if Microspherix desired more time to file its own full briefing on this issue, Merck would be amenable to it, but Microspherix rejected Merck’s proposal. *Id.*

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Sincerely,

s/ David N. Draper
David N. Draper⁸
Attorney for Microspherix

⁸ I certify that I caused a copy of this letter and any accompanying exhibits to be served on opposing counsel of record by NEF through filing the same on the Court's CM/ECF system.